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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,194	12/06/2001	Kevin P. Baker	GNE.2830PIC6	3544
30313	7590	03/22/2004	EXAMINER	
KNOBBE, MARTENS, OLSON & BEAR, LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			HAMUD, FOZIA M	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/007,194

Applicant(s)

BAKER ET AL.

Examiner

Fozia M Hamud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 08/30/02
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-27 and adding new claims 28-33, filed on 06 December 2001 is acknowledged.

Thus claims 28-33 are pending and under consideration.

2. **Priority:**

- 2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. 09/946,374 filed on 04 September 2001, because, EXAMPLE 150 (Assay #110), which provides a specific and substantial asserted utility or a well established utility for the claimed antibodies, is disclosed on page 512 of Application no. 09/946,374. However, none of the other prior applications disclose this assay. Accordingly, the subject matter defined in claims 27-33, is afforded an effective filing date of 04 September 2001, which is the filing date of the U.S application No. 09/946,374.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 09/04/01, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession of and fully enabled for prior to 09/04/01.

***Claim rejections-35 USC § 112, second paragraph:***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3a. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "specifically" recited in instant claim 33 is a relative term which renders the claims indefinite. The term "specifically" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Appropriate correction is required.

***Claim Rejections - 35 U.S.C. §102(b):***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 28-33 are rejected under U.S.C. § 102 (a) as being anticipated by Baker et al (WO200012708; published 09 March 2000).

Baker et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:116 of the instant application. (See attached copies of the comparison of SEQ ID NO:116 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Baker et al also disclose an antibody that binds to said polypeptide, (page 104-105). Baker et al disclose an antibody fragment, a

monoclonal antibody and a humanized antibody, that bind to a polypeptide that shares 100% identity to the polypeptide of SEQ ID NO:116, (pages 366-369).

Instant claims 28-33 are drawn to an antibody (monoclonal, fragment, humanized or labeled) that binds to the polypeptide of SEQ ID NO:116. Therefore, the Baker et al reference meets all the limitations recited in claims 28-33, because the antibody disclosed in this reference would be expected to bind completely to the polypeptide of SEQ ID NO:116 of the instant application. Therefore, the Baker et al reference anticipates the instant claims 28-33 in the absence of any evidence to the contrary.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

***Claim Rejections - 35 U.S.C. §102(a):***

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6a. Claims 28-33 are rejected under U.S.C. § 102 (a) as being anticipated by Yang et al (WO200151638; published 19 July 2001).

Yang et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:116 of the instant application. (See attached copies of the comparison of SEQ ID NO:116 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'B'). Yang et al also disclose an antibody that binds to said polypeptide, (page 32). Yang et al disclose an antibody fragment, a monoclonal antibody and a humanized antibody, that bind to a polypeptide that shares 100% identity to the polypeptide of SEQ ID NO:116 (pages 61-62).

Instant claims 28-33 are drawn to an antibody (monoclonal, fragment, humanized or labeled) that binds to the polypeptide of SEQ ID NO:116. Therefore, the Yang et al reference meets all the limitations recited in claims 28-33, because the antibody disclosed in this reference would be expected to bind completely to the polypeptide of SEQ ID NO:116 of the instant application. Therefore, the Yang et al reference anticipates the instant claims 28-33 in the absence of any evidence to the contrary.

**Conclusion:**

7. No claim is allowed.

**Advisory Information:**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
18 March 2004

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

## ALIGNMENTS

Sequence Comparison  
"A"

RESULT 1  
 AAY99372  
 ID AAY99372 standard; Protein; 331 AA.  
 XX  
 AC AAY99372;  
 XX  
 DT 08-AUG-2000 (first entry)  
 XX  
 DE Human PRO1430. (UNQ736) amino acid sequence SEQ ID NO:116.  
 XX  
 KW Human; PRO polypeptide; membrane bound protein; receptor; diagnosis;  
 KW transmembrane; secretion; immunoadhesion; pharmaceutical; screening.  
 XX  
 OS Homo sapiens.  
 XX  
 PN WC200012708-A2;  
 XX  
 XX 09-MAR-2000. ✓  
 PD  
 XX 01-SEP-1999; 99W0-US20111.  
 PF  
 XX 01-SEP-1998; 98US-0098716.  
 PR 01-SEP-1998; 98US-0098749.  
 PR 01-SEP-1998; 98US-0098750.  
 PR 02-SEP-1998; 98US-0098803.  
 PR 02-SEP-1998; 98US-0098821.  
 PR 02-SEP-1998; 98US-0098843.  
 PR 09-SEP-1998; 98US-0099536.  
 PR 09-SEP-1998; 98US-0099596.  
 PR 09-SEP-1998; 98US-0099598.  
 PR 09-SEP-1998; 98US-0099602.  
 PR 09-SEP-1998; 98US-0099642.

XX  
 PA (GETH ) GENENTECH INC.  
 XX  
 PI Baker K, Goddard A, Gurney AL, Smith V, Watanabe CK, Wood WI;  
 XX  
 DR WPI; 2000-237871/20.  
 DR N-PBDB; AAA37054.  
 XX  
 PT New mammalian DNA sequences encoding transmembrane, receptor or  
 PT secreted PRO polypeptides, useful for screening of potential peptide or  
 PT small molecule inhibitors of the relevant receptor/ligand interactions  
 XX  
 XX Claim 12; Fig 66; 773pp; English.  
 PB  
 CC AAA37022 to AAA37144 encode the new isolated human transmembrane,  
 CC receptor or secreted PRO polypeptides given in AAY99340 to AAY99462. The  
 CC transmembrane and receptor PRO proteins can be used for screening of  
 CC potential peptide or small molecule inhibitors of the relevant  
 CC receptor/ligand interactions. The polypeptides and nucleotide sequences  
 CC encoding then have various industrial applications, including uses as  
 CC pharmaceutical and diagnostic agents. AAA37145 to AAA37330 represent  
 CC PCR primers and hybridisation probes used in the isolation of the PRO  
 CC polypeptides from the present invention.  
 XX  
 SQ Sequence 331 AA;

Query Match 100.0%; Score 1695; DB 21; Length 331;  
 Best Local Similarity 100.0%; Pred. No. 4.5e-166;  
 Matches 331; Conservative 0; Mismatches 0; Indels 0; Gaps 0;  
 Qy 1 MSRYLLPLSALGTAGAAVLKDYVTGAGKCSKATIPKTVITGANTGIGQTALELAR 60  
 Db 1 MSRYLLPLSALGTAGAAVLKDYVTGAGKCSKATIPKTVITGANTGIGQTALELAR 60  
 Qy 61 RGGNIIACRDMKCEAAAKDTRGETLNHHVNARHLDLASKSIREFAAKITREERSVDI 120  
 Db 61 RGGNIIACRDMKCEAAAKDTRGETLNHHVNARHLDLASKSIREFAAKITREERSVDI 120  
 Qy 121 LINNAGVRCRHWTTEDGFEMQFVNHLGHFLTNLLDLKLKASAPRIINLSSLAHVAG 180  
 Db 121 LINNAGVRCRHWTTEDGFEMQFVNHLGHFLTNLLDLKLKASAPRIINLSSLAHVAG 180  
 Qy 181 HIDPDLNMQTRKYNKAAAYCQSLAIVLFTKELSRRLQSGSVTVNALHPGVARTELRH 240  
 Db 181 HIDPDLNMQTRKYNKAAAYCQSLAIVLFTKELSRRLQSGSVTVNALHPGVARTELRH 240  
 Qy 241 TGIHSTFSSTTLGPIFWLVKSPELAAQSTYLAVARELADVSGKYFDGLKQKAPAPPA 300  
 Db 241 TGIHSTFSSTTLGPIFWLVKSPELAAQSTYLAVARELADVSGKYFDGLKQKAPAPPA 300  
 Qy 301 EDEEVARRLWASARLVGLEAPSVREQPLPR 331  
 Db 301 EDEEVARRLWASARLVGLEAPSVREQPLPR 331

RESULT 4  
AA05174  
ID AAR05174 standard; Protein; 331 AA.

Sequence Comparison  
"B"

XX AC AAR05174;  
XX DT 12-SEP-2001 (first entry)  
XX DR Human drug metabolising enzyme (DME-5) protein.  
XX KW Human; drug metabolising enzyme; DME-5; immunosuppressive; gene therapy;  
XX cytosolic; autoimmune disorder; inflammatory disorder; atherosclerosis;  
XX osteoporosis; eye disorder; hepatic tumor; Addison's disease; cretinism;  
XX rheumatoid arthritis; acquired immune deficiency syndrome; AIDS; anaemia;  
XX developmental disorder; endocrine disorder; iritis; acromegaly; epilepsy;  
XX thyrotoxicosis; pancreatic disorder; diabetes mellitus; obesity; adenoma;  
XX gastrointestinal disorder; nodular hyperplasia; conjunctivitis; glaucoma;  
XX actinic keratosis; metabolic disorder; dysphagia; anorexia; carcinoma;  
XX cell proliferative disorder.

XX OS Homo sapiens.  
XX FH Key Location/Qualifiers  
XX FT Peptide 1..17  
XX FT /label= Signal\_peptide  
XX FT Protein 18..331  
XX FT /note= "Mature drug metabolising enzyme (DME-5) protein"

XX PN WO200151638-A2 ✓  
XX PD 19-JUL-2001 ✓  
XX PF 12-JAN-2001; 2001WO-US01174.  
XX PR 14-JAN-2000; 2000US-0176139.  
XX PR 21-JAN-2000; 2000US-0177443.  
XX PR 28-JAN-2000; 2000US-0178574.  
XX PA (INCY-) INCYTE GENOMICS INC.

XX PI Yang J, Baughn MR, Burford N, Au-Young J, Lu DAM, Reddy R;  
XX PI Ring HZ, Hillman JL, Yue H, Azimzai Y, Yao MG, Gandhi AR;  
XX PI Nguyen DB, Tang YT, Lal P, Bandman O;

XX DR WFI; 2001-425874/45.  
XX DR N-PSDB; AAD09940.

XX PT Drug metabolizing enzymes and encoding polynucleotides, useful for  
XX diagnosing, treating and/or preventing autoimmune, inflammatory, cell  
XX proliferative, developmental, endocrine, eye, metabolic, and  
XX gastrointestinal disorders -

PS Claim 1; Page 139-140; 133pp; English.

XX CC The present sequence is human drug metabolising enzyme (DME-5) protein.  
XX CC Human DME and its nucleic acid molecule are useful for the diagnosis,  
XX CC treatment and prevention of disorders associated with increased or  
XX CC decreased expression of DME. Examples of such disorders include,  
XX CC autoimmune/inflammatory disorder such as acquired immune deficiency  
XX CC syndrome (AIDS), rheumatoid arthritis, osteoporosis; cell proliferative  
XX CC disorder such as actinic keratosis, atherosclerosis; developmental  
XX CC disorder such as epilepsy, anaemia; endocrine disorder such as  
XX CC acromegaly, cretinism, thyrotoxicosis; pancreatic disorder such as  
XX CC diabetes mellitus; eye disorder such as conjunctivitis, glaucoma, iritis;  
XX CC metabolic disorder such as Addison's disease, obesity; gastrointestinal  
XX CC disorder such as anorexia, dysphagia and hepatic tumours including  
XX CC nodular hyperplasia, adenomas and carcinomas. DME DNA is useful for  
XX CC creating "knockin" humanised animals (pigs) or transgenic animals (mice  
XX CC or rats) to model human disease. DME DNA is also in useful is gene  
XX CC therapy. DME and its immunogenic fragments are useful for screening  
XX CC libraries of compounds in several drug screening assays.

XX SQ Sequence 331 AA;  
Query Match 100.0%; Score 1695; DB 22; Length 331;  
Best Local Similarity 100.0%; Pred. No 4.5e-166;  
Matches 331; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Oy 1 MSRYLLPLSALGTVAGAAVLLKDYVTGQACPSKATIPGKTIVITGANTGIGKOTALELAR 60  
Db 1 MSRYLLPLSALGTVAGAAVLLKDYVTGQACPSKATIPGKTIVITGANTGIGKOTALELAR 60  
Oy 61 RQGNITLACDMKCEAAAKDIRGETLNHHVNAHRLDLASLKIREFPAKIIEREERVDI 120  
Db 61 RQGNITLACDMKCEAAAKDIRGETLNHHVNAHRLDLASLKIREFPAKIIEREERVDI 120  
Oy 121 LNNAGVMRCFHWTTEDGFEMQGVNHLGHLLTNLLDKLKASAPSRITNLSLHAYG 180  
Db 121 LNNAGVMRCFHWTTEDGFEMQGVNHLGHLLTNLLDKLKASAPSRITNLSLHAYG 180  
Oy 181 HIDPDDLNNWOTRYNTKAAVCQSKLAIVLPTKLSRRLQSGSVTVNALHPGVARTELGRH 240  
Db 181 HIDPDDLNNWOTRYNTKAAVCQSKLAIVLPTKLSRRLQSGSVTVNALHPGVARTELGRH 240  
Oy 241 TGTHGSTFSSTILGPIFWLLVKPSLEAQAQSTYLAVAEELADVSGKYFDGLKQKAPAPEA 300  
Db 241 TGTHGSTFSSTILGPIFWLLVKPSLEAQAQSTYLAVAEELADVSGKYFDGLKQKAPAPEA 300  
Oy 301 EDEHVARRLWASARLVGLEAPSVREQLPR 331  
Db 301 EDEHVARRLWASARLVGLEAPSVREQLPR 331